

**SECTIONS OF FEDERAL FOOD, DRUG, AND COSMETIC ACT INVOLVED IN VIOLATIONS
REPORTED IN D.D.N.J. NOS. 5581-5620**

Adulteration, Section 501(b), the article purported to be and was represented as a drug, the name of which is recognized in an official compendium (United States Pharmacopeia and National Formulary), and its strength differed from, and its quality and purity fell below, the standard set forth in such compendium; and Section 501(c), the article was not subject to the provisions of Section 501(b), and its strength and quality differed from that which it purported or was represented to possess.

Misbranding, Section 502(a), the labeling of the article was false and misleading; Section 502(b), the article was in package form, and it failed to bear a label containing (1) the name and place of business of the manufacturer, packer, or distributor, and (2) an accurate statement of the quantity of contents; Section 502(d), the article contained a chemical derivative of barbituric acid, and its label failed to bear the name, and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming"; Section 502(e) (2), the article was a drug not designated solely by a name recognized in an official compendium and was fabricated from two or more ingredients, and its label failed to bear the common or usual name of each active ingredient; Section 502(f) (1), the labeling of the article failed to bear adequate directions for use; Section 502(f) (2), the labeling of the article failed to bear adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users; and Section 503(b) (4), the article was a drug subject to Section 503(b) (1), and its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

New-drug violation, Section 505(a), the article was a new drug within the meaning of Section 201(p), which was introduced into interstate commerce, and an application filed pursuant to Section 505(b) was not effective with respect to such drug.

NEW DRUGS SHIPPED WITHOUT EFFECTIVE APPLICATION

5581. Clarimycin. (F.D.C. No. 41325. S. No. 83-423 M.)

QUANTITY: 35 display cartons, each containing 6 btl., at Columbus, Ohio.

SHIPPED: 11-22-57, from Jersey City, N.J., by Merritt Corp.

LABEL IN PART: (Btl.) "5 drams Clarimycin Anti-Biotic Acne Lotion * * *

Active ingredients: Neomycin Sulphate, Allantoin."

LIBELED: 1-7-58, S. Dist. Ohio.

CHARGE: 505(a)—The article, when shipped, was a new drug which may not be shipped in interstate commerce since an application filed pursuant to law was not effective with respect to the drug.

DISPOSITION: 8-20-58. Consent—destruction.

5582. Clarimycin. (F.D.C. No. 41372. S. No. 60-378 M.)

QUANTITY: 366 display cards, each containing 1 btl., at Detroit, Mich.

SHIPPED: 11-25-57, from Jersey City, N.J., by Merritt Corp.

LABEL IN PART: (Btl.) "Contents: 5 drams Clarimycin Anti-Biotic Acne Lotion * * * Active Ingredients: Neomycin Sulphate, Allantoin."

LIBELED: 1-22-58, E. Dist. Mich.